BASIC CARE DAYTIME SEVERE COLD NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride
L. Perrigo Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Amazon Day Time Severe Cold Night Time Cold & Flu Drug Facts

Active ingredients (in each caplet) - DAY TIME Severe Cold

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients (in each caplet) – NIGHT TIME Cold & Flu

Acetaminophen 325 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 5 mg

Purposes - DAY TIME Severe Cold

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purposes - NIGHT TIME Cold & Flu

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- cough (DAY TIME Severe Cold only)
- minor aches and pains
- headache
- sore throat
- runny nose and sneezing (NIGHT TIME Cold & Flu only)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of

bothersome mucus and make coughs more productive (DAY TIME Severe Cold only)
- temporarily reduces fever

Warnings

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin (NIGHT TIME Cold & Flu only)
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking these products.
- if you have ever had an allergic reaction to these products or any of their ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma (NIGHT TIME Cold & Flu only)
- a breathing problem such as emphysema or chronic bronchitis (NIGHT TIME Cold & Flu only)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (DAY TIME Severe Cold only)
- cough that occurs with too much phlegm (mucus) (DAY TIME Severe Cold only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (NIGHT TIME Cold & Flu only)

When using these products

- do not use more than directed
- excitability may occur, especially in children (NIGHT TIME Cold & Flu only)
- marked drowsiness may occur (NIGHT TIME Cold & Flu only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (NIGHT TIME Cold & Flu only)
- avoid alcoholic drinks (NIGHT TIME Cold & Flu only)
- be careful when driving a motor vehicle or operating machinery (NIGHT TIME Cold & Flu only)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition. (DAY TIME Severe Cold only)

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 10 caplets in any 24-hour period
- adults and children 12 years of age and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

- **each caplet contains:** sodium 4 mg (DAY TIME Severe Cold only)
- store at 20-25°C (68-77°F)

Inactive ingredients - DAY TIME Severe Cold

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake,

maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Inactive ingredients – NIGHT TIME Cold & Flu

crospovidone, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Mucinex® Fast-Max® Day Time & Night Time active ingredients

Maximum Strength

For Ages 12+

daytime severe cold

Acetaminophen

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

Pain Reliever

Fever Reducer

Cough Suppressant

Expectorant

Nasal Decongestant

Relieves Aches, Fever & Sore Throat

Controls Cough

Relieves Nasal & Chest Congestion

Thins & Loosens Mucus

actual size

20 CAPLETS

For Ages 12+

night time cold & flu

Acetaminophen

Diphenhydramine HCl

Phenylephrine HCl

Pain Reliever

Fever Reducer

Antihistamine

Nasal Decongestant

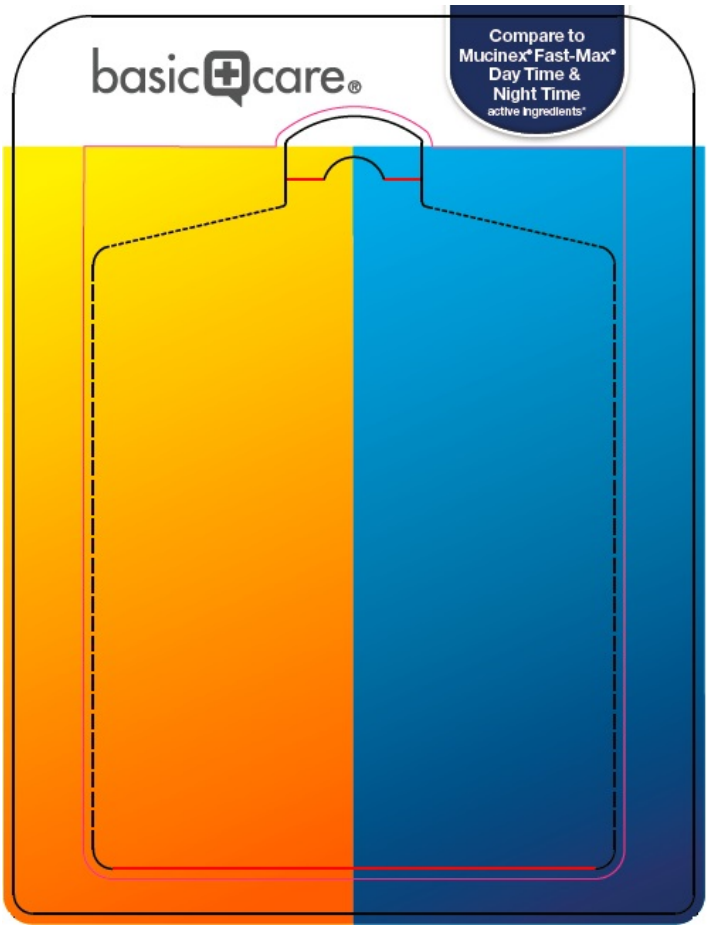
Relieves Aches, Fever & Sore Throat

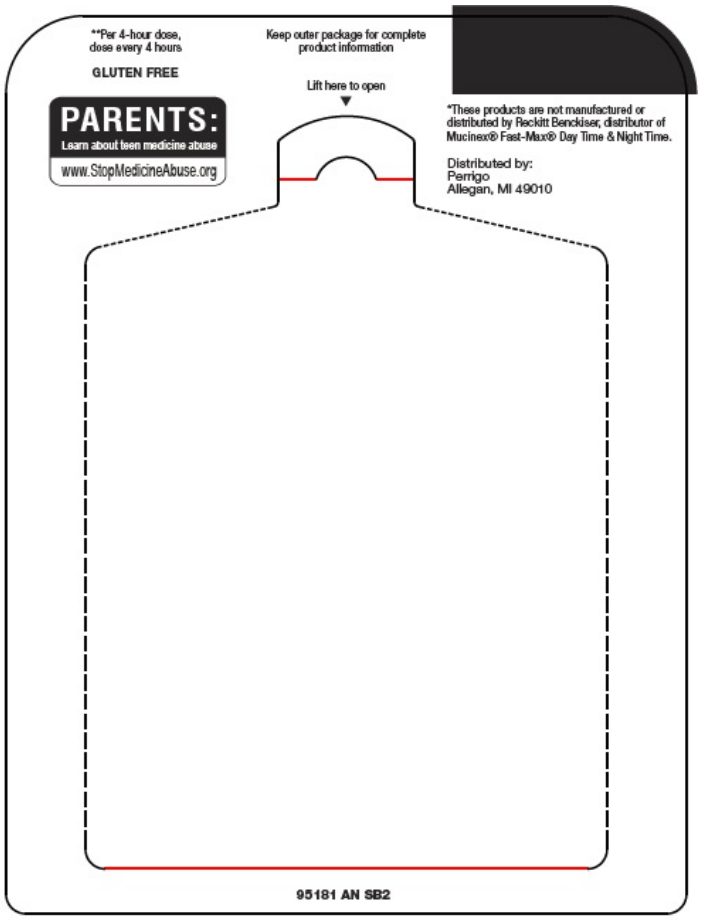
Relieves Nasal Congestion

Relieves Runny Nose & Sneezing

actual size

10 CAPLETS





Maximum Strength**

NDC 0113-7951-81

For Ages 12+

day time severe cold

Acetaminophen
Dextromethorphan HBr
Guaifenesin
Phenylephrine HCl

Pain Reliever
Fever Reducer
Cough Suppressant
Expectorant
Nasal Decongestant

Relieves Aches, Fever & Sore Throat
Controls Cough
Relieves Nasal & Chest Congestion
Thins & Loosens Mucus

actual size

20 CAPLETS

For Ages 12+

night time cold & flu

Acetaminophen
Diphenhydramine HCl
Phenylephrine HCl

Pain Reliever
Fever Reducer
Antihistamine
Nasal Decongestant

Relieves Aches, Fever & Sore Throat
Relieves Nasal Congestion
Relieves Runny Nose & Sneezing

actual size

10 CAPLETS

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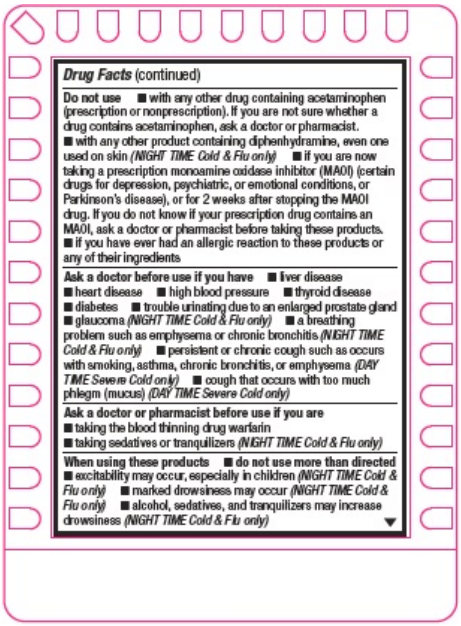

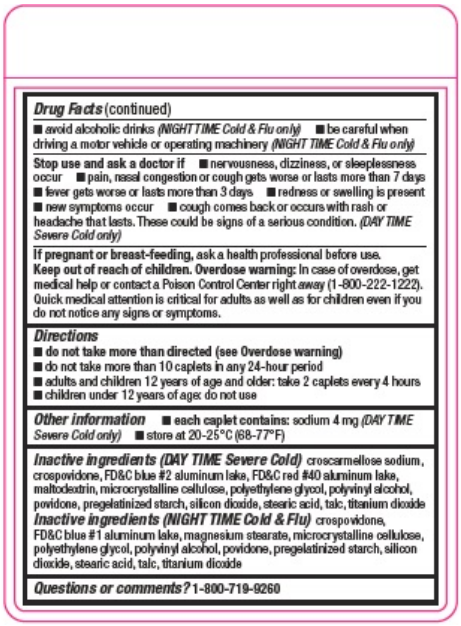

BASIC CARE DAYTIME SEVERE COLD NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0113-7951

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-7951-81	1 in 1 KIT; Type 0: Not a Combination Product	01/24/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 BLISTER PACK	20
Part 2	5 BLISTER PACK	10

Part 1 of 2

BASIC CARE DAY TIME SEVERE COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	L922
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		10 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

Part 2 of 2

BASIC CARE NIGHT TIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/24/2019	

Labeler - L. Perrigo Company (006013346)

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